
From: compliance <compliance@Safechain.com>
Sent: Tue 11/24/2020 1:31:26 PM (UTC)
To: Pat Boyd <PatB@Safechain.com>, Charles Boyd <CharlesB@Safechain.com>
Cc: compliance <compliance@Safechain.com>
Subject: FW: Sale of Counterfeit BIKTARVY® Lot # CCXKVA [GILEAD-LDMS.FID511078]
Attachment: Nov. 23, 2020 Letter to Safe Chain Solutions_ LLC(4125223.1).pdf

Good morning,

Attached is a letter from Gilead regarding counterfeit drugs. Please let me know how you would like us to respond to this.

Thanks,



Abbie Divilio | Director of Compliance
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 x1017 | fax: 866.930.1128
www.SafeChain.com | [LinkedIn](#)

From: Peter Colosi <peter.colosi@gilead.com>
Sent: Monday, November 23, 2020 7:22 PM
To: Care <care@safechain.com>; compliance <compliance@Safechain.com>
Subject: Sale of Counterfeit BIKTARVY® Lot # CCXKVA [GILEAD-LDMS.FID511078]

To Whom It May Concern:

Please see the attached correspondence. We look forward to your reply no later than December 7, 2020.

Pete Colosi
415-341-3818

GOVERNMENT
EXHIBIT

203

1:24-cr-20255-WPD



Anti-Counterfeiting

VIA EMAIL (care@safechain.com; compliance@safechain.com)

November 23, 2020

Safe Chain Solutions, LLC
822 Chesapeake Drive
Cambridge, MD 21613

Safe Chain Solutions, LLC
PO Box 479
Souderton, PA 18694

InCorp Services, Inc.
1519 York Road
Lutherville, MD 21093

Re: Sale of Counterfeit BIKTARVY® Lot # CCXKVA

Dear Legal Department:

I am an attorney with Gilead's Anti-Counterfeiting and Brand Protection Team and I write for two reasons: (1) to follow up on correspondence regarding BIKTARVY® (Lot # CDGXKA) and (2) to seek your cooperation with our investigation into BIKTARVY (Lot # CCXKVA).

First, on or about Oct. 5, 2020, Dakota Flowers and Abbie Divilio contacted Gilead in an attempt to verify the Drug Supply Chain Security Act Document attached hereto. Gilead responded that the "information contained in the [Document was] inconsistent with our records," stated that if the Document referenced a Gilead product in Safe Chain's "possession or control, . . . it should be treated as illegitimate product and quarantined and should be reported to the FDA via a Form FDA 3911," and that you should share with us a copy of any such form you file with the FDA. Please provide an update on this matter, including providing us with a copy of any documentation submitted to the FDA.

Second, we are investigating a bottle of BIKTARVY® (Lot # CCXKVA) that was dispensed by White Cross Pharmacy (602 Main St., Brawley, CA 92227). The bottle in question contained foreign tablets instead of BIKTARVY tablets. Because foreign substances were contained within the bottle, the GILEAD, BIKTARVY, and "Leaf and Shield" trademarks found on the bottle are counterfeit.¹

White Cross provided the attached invoice showing that it purchased two bottles of BIKTARVY (Lot # CCXKVA) from Safe Chain Solutions, LLC, 822 Chesapeake Drive, Cambridge, MD 21613.

Because Safe Chain Solutions has been identified as a possible source of the counterfeit BIKTARVY at issue, we require your assistance in our investigation. Please confirm the invoice is accurate to the extent it indicates that you sold Gilead medicine, including BIKTARVY Lot# CCXKVA, to White Cross. Assuming you did sell this Gilead medicine to White Cross, please provide us with all information, correspondence, and documentation surrounding your source(s) of this Gilead medicine, including BIKTARVY Lot # CCXKVA. Please also provide any contact

¹ See *United States v. Petrosian*, 126 F.3d 1232, 1233-34 (9th Cir. 1997) (holding that a Coca-Cola trademark on a genuine bottle became spurious as a result of defendant filling that bottle with non-Coca-Cola and selling it as if it was genuine).

information, including phone numbers, addresses, or names of individuals that would aid us in contacting any of your sources.

Please note that the sale of counterfeit medicine in the United States is illegal and presents a significant threat to public health. As former FDA Commissioner Scott Gottlieb, M.D., stated:²

We see a world where the risk from counterfeit drugs is increasing rapidly. Where the means to produce counterfeits and distribute them through sophisticated, illegal networks is increasing. And the volume is also rising sharply. We have numbers that speak to these risks. We have enforcement work underway that'll -- unfortunately -- illustrate that these concerns are real.

Gilead takes the risks of counterfeit medicine seriously. Exposing patients to potential injury from taking what they thought were genuine Gilead medicine strikes at the core of our mission and the relationship of trust that our company has worked for years to develop. Patients come first at Gilead, and we hope that your organization likewise would like to avoid potential harm to patients by dispensing counterfeit medicine in the future.

Our concerns are also grounded in federal and state law.

- The Federal Food, Drug, and Cosmetic Act establishes both civil and criminal penalties for sales of adulterated, misbranded, and counterfeit drugs.³ Congress has specifically imposed criminal penalties on any person who "intentionally . . . traffics in a drug and knowingly uses a counterfeit mark on or in connection with such drug."⁴
- Maryland Criminal Code § 8-611(b) prohibits the manufacturing, advertising, possession with intent to sell, offering for sale, or the sale of any product "that the person knows" bears a counterfeit trademark.
- Individuals injured as a result of ingesting adulterated, misbranded, counterfeit, and otherwise illegal drugs may themselves have claims against the entities that sold the products.

Importantly, Gilead itself has legal remedies to protect its interests. Using Gilead's registered trademarks to sell and/or distribute medicine that is not legitimate may support Gilead's claims for trademark infringement, trademark dilution, unfair competition, and trading in counterfeit goods under both state and federal law.

Due to the public health and legal risks associated with selling illegitimate or counterfeit products, we look forward to your cooperation in this investigation and we strongly encourage you to buy Gilead products only from authorized distributors which are identified on Gilead's website (<https://www.gilead.com/purpose/medication-access/authorized-distributors>).

² See Remarks by Dr. Gottlieb on Enhancing Drug Distribution Security (February 28, 2018), available at: <https://www.fda.gov/NewsEvents/Speeches/ucm598719.htm>.

³ See, e.g., 21 U.S.C. § 331. Whether and how federal law enforcement agencies choose to enforce this and other violations of federal law cited in this letter are solely for the agencies themselves to determine.

⁴ See 18 U.S.C. § 182320(a)(4).

This letter is without prejudice to any rights and remedies of Gilead, all of which are expressly reserved. I look forward to a response and the requested information no later than December 7, 2020.

Sincerely,

Peter M. Colosi

Peter M. Colosi
Senior Counsel, Anti-Counterfeiting
Gilead Sciences, Inc.
Peter.colosi@gilead.com
650-389-8733


Pharmacy's Invoice & License (PR-195835)

Invoice with lot number (CCXKVA) that matches the complaint bottle's lot number.

Safe Chain Solutions		Invoice		01129926 Page: 1					
SAFE CHAIN SOLUTIONS, LLC 822 CHESAPEAKE DRIVE CAMBRIDGE, MD 21613 Tel: 855-437-5727 Fax: 855-614-4118 RS0477617		Remit To: Safe Chain Solutions, LLC PO Box 479 Souderton, PA 18964 Tel: 855-437-5727 Fax: 855-614-4118		www.safechain.com accounting@safechain.com					
Bill-to: 27-CA0130 WHITE CROSS PHARMACY - BRAWLEY 1222 W 5TH ST ATTN: RAJ LUNAGARIA SAN BERNARDINO CA 92411		Ship-to: PHAR 001 WHITE CROSS PHARMACY 602 MAIN ST ATTN: SHANE JEROMINSKI BRAWLEY CA 92227							
Invoice Date:	07/29/20	Salesman:	LEGACY - HIV						
Ship Date:	07/29/20	Ship Via:	UPS NEXT DAY SAVER						
Our Order No:	01S27133003	Customer Order #:	VERBAL						
		Terms:	NET 15						
License	PHY39991 Exp: 04/01/21		LicExp:04/01/21						
Special Instructions:	overnight n/c - Net 15								
Line:	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	G61958-2501-01 BIKTARVY TAB 30CT 50/200/25 MG NDC#: 61958-2501-01 Prod Strength: 50-200-25 MG Prod Size: 30 EA Lot #: CCXKNA Expiration Date: 06/30/21 Lot #: CCXKPA Expiration Date: 06/30/21 Lot #: CCXKVA Expiration Date: 06/30/21	8	EA	8	EA	0	2995.44	EA	23,963.52
				2					
				4					
				2					
	SUB TOTAL								23,963.52
	INVOICE TOTAL								\$23,963.52
	CARTON TRACKING NUMBERS: CTN#1 127156792990483589 Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for CA - Destination PHY39991 Exp 04/01/21 PLEASE NOTE OUR NEW REMIT TO ADDRESS								
rtions: 1		Weight: 1.3							
* Non-Taxable									
** REPRINT (1)									

Pharmacy's Invoice & License (PR-195835)

Invoice with lot numbers that do not match the complaint bottle's lot number (CCXKVA).

 SafeChain Solutions		<h1>Invoice</h1>		Inv Number 01129915 Page: 1					
SAFE CHAIN SOLUTIONS, LLC 822 CHESAPEAKE DRIVE CAMBRIDGE, MD 21613 Tel: 855-437-5727 Fax: 855-614-4118 RS0477617		Remit To: Safe Chain Solutions, LLC PO Box 479 Souderton, PA 18964 Tel: 855-437-5727 Fax: 855-614-4118		www.safechain.com accounting@safechain.com					
Bill-to: 27-CA0130 WHITE CROSS PHARMACY - BRAMLEY 1222 W 5TH ST ATTN: RAJ LUNAGARIA SAN BERNARDINO CA 92411		Ship-to: FRAR 001 WHITE CROSS PHARMACY 602 MAIN ST ATTN: SHANE JEROMINSKI BRAMLEY CA 92227							
Invoice Date: 07/29/20 Ship Date: 07/29/20 Our Order No: 01527647002		Salesman: LEGACY - HIV Ship Via: UPS Next Day Customer Order #: VERBAL Terms: NET 15							
License: PHY39991 Exp: 04/01/21 Special Instructions: overnight N/C - Net 15		LicExp: 04/01/21							
Line	Item Number / Description	Ordered	UM	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	G61958-2501-01 BIKTARVY TAB 30CT 50/200/25 MG NDC#: 61958-2501-01 Prod Strength: 50-200-25 MG Prod Size: 30 EA Lot #: CCZBSA Expiration Date: 07/31/21 Lot #: CCZBXA Expiration Date: 07/31/21	18	EA	18	EA	0	2995.44	EA	53,917.92
				16					
				2					
	SUB TOTAL								53,917.92
	INVOICE TOTAL								\$53,917.92
CARTON TRACKING NUMBERS: CTN#1 137156792491467274 Additional License Information State License for MD - Origin D03211 Exp 05/31/21 State License for CA - Destination PHY39991 Exp 04/01/21 PLEASE NOTE OUR NEW REMIT TO ADDRESS									
Cartons: 1		Weight: 3.4		* Non-Taxable ** REPRINT (1)					